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4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-D-0544]

Guidance for Industry on Toll-Free Number Labeling and Related Requirements for Over-the-Counter and Prescription Drugs Marketed With Approved Applications; Small Entity Compliance Guide; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for small business entities entitled "Toll-Free Number Labeling and Related Requirements for Over-the-Counter and Prescription Drugs Marketed With Approved Applications; Small Entity Compliance Guide." This guidance is intended to help small businesses understand and comply with the requirements of the final rule regarding labeling of drugs with a toll-free number for adverse event reporting, which was published in the Federal Register on October 28, 2008 (final rule). The guidance describes certain requirements of the final rule in plain language and provides answers to common questions on how to comply with the rule. FDA prepared this guidance in accordance with the Small Business Regulatory Fairness Act.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993-0002. Send one

self-addressed adhesive label to assist that office in processing your requests. See the SUPPLEMENTARY INFORMATION section for electronic access to the guidance document.

Submit electronic comments on the guidance to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

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10903 New Hampshire Ave.,

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301-796-2090.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for small business entities entitled "Toll-Free Number Labeling and Related Requirements for Over-the-Counter and Prescription Drugs Marketed With Approved Applications; Small Entity Compliance Guide."

This guidance summarizes the final rule published in the Federal Register of October 28, 2008 (73 FR 63886), which requires the labeling of each human drug product for which an application is approved under section 505 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) to include: (1) The toll-free number maintained by FDA for the purpose of receiving reports of adverse events regarding drugs and (2) a statement that the number is to be used for

reporting purposes only, and not to receive medical advice. The final rule requires that the toll-free number and reporting information be:

● Included in all FDA-approved Medication Guides for products approved under section 505,

● Provided to patients by authorized dispensers or pharmacies with each prescription drug product approved under section 505, and

● Included in the labeling of certain over-the-counter drugs approved under section 505.

FDA has previously issued a guidance for industry entitled "Medication Guides—Adding a Toll-Free Number for Reporting Adverse Events" (June 2009) to assist new drug application holders with revising FDA-approved Medication Guides to comply with the first of these requirements. This guidance is intended to assist small businesses and others with implementing the two other requirements in the final rule: Distribution of the toll-free number information to patients with each prescription (or refill) and adding the toll-free number information to the labeling of certain OTC drugs.

FDA is issuing this small entity compliance guide as level 2 guidance consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency's current thinking on side effects statement requirements as set forth in the final rule. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see ADDRESSES) either electronic or written comments regarding this document. It is only

necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday

III. Electronic Access

Persons with access to the Internet may obtain the document at either http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm or http://www.regulations.gov.

Dated: June 11, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

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